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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,793	05/30/2001	Stephen Joseph Vesper	VESPER1	5682

1444 7590 06/19/2003

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	13

DATE MAILED: 06/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/866,793	Vesper
Examiner	**Art Unit**
Patricia A. Duffy	1645

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

FILE COPY

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 8, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *3-5 and 19-21* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *3-5 and 19-21* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *9*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The Examiner of U.S. Patent application SN 09/866,793 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Patricia A. Duffy, Group 1600, Art Unit 1645.

2. For clarification of the record, the amendment filed 7-8-02 has been entered into the record. The notice of non-responsive amendment mailed 9-16-02 has been voided. Further, the interview summary of 2-3-03 is moot in view of the entry of the amendment.

3. Claims 3-5 and 19-21 are pending and under examination.

4. All previous rejections of record are withdrawn in view of the new rejections set forth below. All arguments set forth therein are moot in view of the removal of these rejections.

Information Disclosure Statement

5. The information disclosure statement filed April 17, 2002 has been considered an initialed copy is enclosed.

Claim Rejections - 35 U.S.C. § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3-5 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 3-5, the claims are indefinite in the recitation of "antibodies to fungal hemolysin". It is unclear what is meant by "to" is this specific binding of the antibody to the fungal hemolysin. It is unclear what is meant by "active fragments thereof" because it is unclear what "activity" is demonstrated by the fragment. It is also unclear what is meant by "presence of antigens to fungal hemolysin" encompasses because antigen lacks antecedent basis in the claims and the antibody is "to" fungal hemolysin. Does the antibody specifically bind fungal hemolysin or any antigen ? What are "antigens to fungal hemolysin". Further, detection of the label can not distinguish between bound an unbound antigen it merely provides the indication of the presence of the labeled antibody and as such it is completely unclear how this assay functions when labeled antibody is combined with a sample from said mammal and the label is detected. The assay does not distinguish between labeled antibodies "to fungal hemolysin" that is presumably specifically bound to an "antigen to fungal hemolysin" and label that is presumably not bound to an "antigen to

fungal hemolysin". In view of the confusing nature of the claims, one of skill in the art would not be able to ascertain the metes and bounds of the claimed invention.

As to claims 19-21, the claims are indefinite in the recitation of "antibodies to fungal hemolysin". It is unclear what is meant by "to", is this specific binding of the antibody to the fungal hemolysin ? It is unclear what is meant by "active fragments thereof" because it is unclear what "activity" is demonstrated by the fragment. It is also unclear what is meant by "presence of antigens to fungal hemolysin" encompasses, because antigen lacks antecedent basis in the claims and the antibody is "to" fungal hemolysin. Does the antibody specifically bind fungal hemolysin or any antigen ? What are "antigens to fungal hemolysin". Further, detection of the label can not distinguish between bound an unbound antigen it merely provides the indication of the presence of the labeled antibody and as such it is completely unclear how this assay functions when labeled antibody is combined with a sample from said mammal and the label is detected. The assay does not distinguish between labeled antibodies "to fungal hemolysin" that is presumably specifically bound to an "antigen to fungal hemolysin" and label that is presumably not bound to an "antigen to fungal hemolysin". Further, it completely confusing as to what the purpose of the "...wherein the fungal hemolysin is isolated by culturing a strain of fungus, removing cells and debris from the culture to recover supernatant, and isolating hemolytically active

fractions of fungal hemolysin" because the fungal hemolysin is present or not in a sample from a mammal. Therefore, it is unclear how this contributes or in fact limits the method of the claimed invention, because the fungal hemolysin is to be detected in a sample from a mammal, and not from a cultured fungus. In view of the confusing nature of the claims, one of skill in the art would not be able to ascertain the metes and bounds of the claimed invention.

Claim Rejections - 35 U.S.C. § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the

applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 2-3 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakaguchi et al (Japanese Journal of Medical Mycology, 25(3):Abstract, 1984) in view of Harlow et al (Antibodies A Laboratory Manual, Cold Spring Harbor Press, 1989, pages 390-393).

The claims are drawn to a method for determining if a mammal has been exposed to a hemolysin-producing fungus comprising contacting a sample from the mammal with labeled antibodies "to" fungal hemolysin and detecting the label to determine the presence of "antigens to fungal hemolysin". Further, as to claim 19-21, the wherein clause can not be interpreted because the hemolysin is in the sample from the mammal and not provided in a culture supernatant and this apparent provision can not be interpreted as it relates to detection of a fungal hemolysin in a mammalian sample.

Sakaguchi et al teach the immunohistochemical detection of the secretion of Asp-hemolysin in tissues (i.e. the instant sample) from a mouse infected with *Aspergillus fumigatus* (i.e. the instant mammal). The immunohistochemical method uses and indirect enzyme labeled peroxidase binding IgG antibody (see English Abstract). The method

differs by labeling the second or indirect antibody, rather than the primary or binding antibody.

Harlow et al teaches that in immunohistochemical techniques the antibodies can be labeled directly. Harlow et al teach that both the direct and indirect methods are in common use and that the labeling of the primary or binding antibody provides for the advantage of cleaner signals with lower background (see page 390, first full paragraph). Further, Harlow et al teaches that the labeled primary antibodies may be labeled with enzymes, fluorochromes or iodine (see page 392, section 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time that the invention was made to modify the immunohistochemical assay for the detection of Asp-hemolysin in a mammalian sample because Harlow et al teaches that labeled primary antibody provides for the advantage of cleaner signals with lower background and that both the direct and indirect methods are in common usage. It would have also been *prima facie* obvious to substitute the enzyme label in the method as combined supra for any other appropriate label according to Harlow et al (fluorochromes or iodine) to label the primary antibody for detection of the Asp-hemolysin because Harlow et al teach that these are conventional alternative labels for a labeled primary antibody for histochemistry.

Citation of Relevant Art

10. A copy of Ishida et al (of record) and the English translation is provided herein to demonstrate that Ishida et al does not use a sample from a mammal and as such Ishida et al can not be anticipatory for the claimed invention, that specifically requires a sample from a mammal.

Status of Claims

11. No claims are allowed.

12. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
June 9, 2003

Patricia A. Duffy, Ph.D.
Primary Examiner